PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2005/000028	09.01.2005	09.01.2004

International Patent Classification (IPC) or both national classification and IPC
C12N9/18, A61K38/46

Applicant
YISSUM RESEARCH DEVELOPMENT COMPANY OF THE...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2005/000028

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

   see separate sheet

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1,3,11-23, 33-57, 58-65

because:

☒ the said international application, or the said claims Nos. 11-23, 33-57 (IA) relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1,3,11,33,46,65 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☒ the claims, or said claims Nos. 1,3,11,33,46,65 are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 58-64

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-57,65-77

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-57, 65-77
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	5,11-57,65-77
	No:	Claims	1-4,6-10
Industrial applicability (IA)	Yes:	Claims	1-10,24-32,65-77
	No:	Claims	

2. Citations and explanations

   see separate sheet

Additional remarks to item I

This first written opinion was established on the application documents as filed.

Additional remarks to item III

I. Claims 11-23 and 33-57 relate to a subject matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

In addition, the attention of the Applicant is drawn to the fact that no unified criteria exist in PCT for assessment of patentable inventions. The EPO, for example, considers that claims 11-23 and 33-57 as far as they concern a medical treatment relates to a subject-matter considered by the Examining Division of the EPO to be covered by the provisions of Rule 52(4) EPC. Consequently, in an eventual subsequent examination in regional phase, this invention would not be considered as being susceptible of industrial application.

ii. Present claims 1, 3, 33, 46 and 65 relate to a product (a BchE derived peptide) defined by reference to a desirable characteristic or property, namely, the capability of preventing and/or reversing amyloid fibril formation.

The claims cover all products having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only one BchE derived peptide. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the product by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the peptide having the sequence as forth in SEQ ID No 1.

Additional remarks to item IV

The objection as lack of unity raised in the international search report (ISR) is maintained. The reasons for the objection are the same as those indicated in the ISR.

As the Applicant has not had a search report drawn up on invention 2 (Rule 66.2 PCT), the application will be prosecuted on the basis of the invention in respect of which a search has already been carried out, in the present case invention 1.

Additional remarks to item V

The following document is referred to in the present written opinion:

D1: EP-A-1 270 594 (SYNAPTICA LIMITED) 2 January 2003 (2003-01-02)

I. D1 discloses a 42 amino acid long BchE derived peptide that comprises the peptide sequence as set forth in SEQ ID No 1.

The capability of a peptide of preventing or reversing amyloid fibril formation being an intrinsic property of said peptide, this Authority is of the opinion that the peptide shown in D1 is also capable of preventing or reversing amyloid fibril formation.
In view of D1, claim 1 lacks novelty (Article 33(2) PCT).

ii. The Applicant merely showed that a 41 amino acid peptide has the claimed property. The capability of the other peptides (SEQ ID No 8 to SEQ ID No 20302) of preventing amyloid fibril formation was not assessed so that this Authority wonders whether said peptides exhibit or not the same property and especially the shortest peptides that are not more than 6 amino acids long.
This Authority is of the opinion that the arbitrary chosen minimum length, namely, 6 residues, is merely based on the fact that 6 residues is the minimum length required in the present case for a peptide to be novel over the prior art.
Said length is not based on the biological activity of said peptides.
As a consequence, the different peptides described in SEQ ID No 8 to SEQ ID No 20302 are considered as being merely further BChE peptides.
Therefore, claim 2 is not inventive (Article 33(3) PCT).

iii. The addition of a peptide to a pharmaceutical composition is a common practice in the art. Hence, claims 3, 4, 6-10 are not inventive.

Further comment

The attention of the Applicant is drawn to the fact that a reply to this opinion is only expected if he intends to file a chapter II demand.